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MS APPEAL BRIEF - PATENTS
PATENT
1422-0507P

IN THE U.S. PATENT AND TRADEMARK OFFICE

In re application of Before the Board of Appeals
Makoto OZEKI et al. Appeal No.:
Appl. No.: 09/980,620 Group: 1615
Filed: December 5, 2001 Examiner: SHEIKH, N.H.
Conf.: 8140
For: COMPOSITIONS FOR PROMOTING SLEEP

APPEAL BRIEF TRANSMITTAL FORM

MS APPEAL BRIEF - PATENTS
Commissioner for Patents
P.O. Box 1450
Alexandria, VA 22313-1450

February 20, 2004

Sir:

Transmitted herewith is an Appeal Brief (in triplicate) on behalf of the Appellants in connection with the above-identified application.

The enclosed document is being transmitted via the Certificate of Mailing provisions of 37 C.F.R. § 1.8.

A Notice of Appeal was filed on December 23, 2003.

Applicant claims small entity status in accordance with 37 C.F.R. § 1.27

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Respectfully submitted,

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A P P E A L B R I E F

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Filed: December 5, 2001 Examiner: Sheikh, H.N.
For: Compositions for Promoting Sleep

APPEAL BRIEF

Commissioner for Patents

February 20, 2004

P.O. Box 1450
Alexandria, VA 22313-1450

Sir:

In response to the Examiner's Office Actions dated June 25, 2003, and the Advisory Action dated November 20, 2003, the following Appeal Brief is respectfully submitted in connection with the above-identified application.

I. Real Party in Interest

The real party in interest of the present invention is Taiyo Kagaku Co. Ltd., of Yokkaichi-shi, Mie, Japan, the assignee of the entire right and interest of the instant application. The assignment of said right and interest was recorded on April 23, 2002 at Reel 012817, Frame 0103.

II. Related Appeals and Interferences

There are no related appeals or interferences pending for the present application.

III. Status of Claims

Claims 1-14 and 16-28 are pending in the present application.

Claims 1-4 are rejected under 35 USC §102(b) as being anticipated by Kakuda '866 (US Patent No. 5,501,866).

Claims 5-14 and 16-28 are rejected under 35 USC §103(a) as being unpatentable over Kakuda '866 in view of Ekanayake '1628 (US Statutory Invention Registration H1628).

Thus, the rejections concerning claims 1-14 and 16-28 are appealed.

IV. Status of Amendments

Subsequent to the Examiner's final rejection of claims 1-28 on June 25, 2003, an after-final response was filed October 27, 2003. An attempt was made to cancel claim 15 and amend claims 21 and 26 in the after final response of October 27, 2003. The Examiner indicated that entry of the amendments of the claims would be made upon filing an appeal.¹ A Notice of Appeal was filed on December 23, 2003.

V. Summary of Invention

The present invention, as recited in claim 1, relates to a sleep-promoting composition comprising theanine (page 1, lines 6-7). As recited in claim 4, the present invention relates to a method for promoting sleep in an individual having sleep disorders, comprising administering an effective sleep promoting amount of theanine to the individual having sleep disorders (page 1, line 7-9, page 3, lines 19-23).

VI. Issues to be considered

Issue 1

Are claims 1-4 properly rejected under 35 USC §102(b) as being anticipated by Kakuda '866 (US Patent No. 5,501,866)?

¹ Accordingly, the Appendix cites the claims as were amended on October 27, 2003.

Issue 2

Are claims 5-14 and 16-28 properly rejected under 35 USC §103(a) as being unpatentable over Kakuda '866 in view of Ekanayake '1628 (US Statutory Invention Registration H1628)?

VII. Grouping of Claims

Appellants respectfully request that the claims be grouped as follows.

Group I - claims 1-3

Group II - claim 4

Group III - claims 5-7, 11, and 16-18

Group IV - claims 8 and 9

Group V - claim 10

Group VI - 12-14, and 19

Group VII - claims 20 and 28

Group VIII - claims 21 and 25-27

Group IX - claims 22-24

VIII. Arguments

Issue 1

The Examiner Has Failed To Establish A Proper 35 USC §102(b) Rejection Over Kakuda '866

Claims 1-4 are rejected under 35 USC §102(b) as being anticipated by Kakuda '866 (US Patent No. 5,501,866).

Group I - claims 1, 2, and 3

Claim 1 recites:

1. A sleep-promoting composition comprising theanine.

The Examiner asserts that "Kakuda disclose [SIC, discloses] a composition that is generic to the issue of sleep-promotion." (see page 6 of the Office Action of June 25, 2003). Appellants strongly disagree. Kakuda '866 simply discloses a caffeine stimulation inhibitor containing theanine. In particular, in the only reference to "sleep" in all of Kakuuda '866, Kakuda '866 discloses:

By refining theanine, frequently contained in caffeine-containing beverages and foods such as tea and coffee, and using it as an active ingredient, in addition to it being able to be used as a harmless additive, by using theanine and/or compositions having theanine as their active ingredient in caffeine-containing beverages and foods, a caffeine stimulation inhibitor can be provided that allows those people who are hypersensitive to caffeine or those people who desire to suppress the action of caffeine (including, but not limited to, those people who desire to drink tea and coffee without impairing sleep) without worry over its effects.

Although the caffeine stimulation inhibitor of the present invention is preferably used as an additive of beverages and foods after processing into liquid, granule or powder form, it may also be individually absorbed in the form of tablets, capsules, granules or syrup. (emphasis added, see column 2, lines 57-63 in Kakuda '866).

From this passage, it should be apparent that Kakuda '866 says nothing of "sleep promotion" (or a "method for promoting sleep") which is an element that appears in independent claim 1. Because claims 2 and 3 are dependent from

claim 1, claims 2 and 3 also must contain the "sleep promoting composition" element. Appellants respectfully point out that "sleep promotion" is not the same as "suppress[ing] the action of caffeine (including, but not limited to, those people who desire to drink tea and coffee without impairing sleep)".

Appellants respectfully submit that "without impairing sleep", as disclosed in Kakuda '866, means that one is able to sleep as if one did not take caffeine. Kakuda '866 discloses that the effect of taking theanine on a person who takes caffeine is to counter the effects of caffeine. In other words, the effects on this person would not differ from the effects felt by an individual who takes neither caffeine nor theanine. Accordingly, Kakuda '866 fails to teach "sleep promotion", but rather only teaches "not impairing sleep" (or the ability to sleep regularly).

Further, Appellants submit that there are many known effects of caffeine, including nervousness, shaking, and alertness. Kakuda '866 discloses ingesting theanine to counter these many known effects (as well as to not impair sleep as was discussed above). Kakuda '866 discloses using theanine with caffeine to counter the effects. Kakuda '866 does not disclose or suggest taking theanine in the absence of caffeine as is present in Examples 3 and 4 of the instant written description. Even in the absence of caffeine, theanine is useful for promoting sleep.

Group II - claim 4

Claim 4 recites:

4. *A method for promoting sleep in an individual having sleep disorders, comprising administering an effective sleep promoting amount of theanine to the individual having sleep disorders.*

Appellants submit that Kakuda '866 fails to disclose or suggest a "method for promoting sleep" as argued above in the section regarding group I. Thus, the arguments, which have been made in group I also apply here.

Appellants respectfully request that claim 4 (*i.e.*, group II) be considered separately from claims 1-3 (*i.e.*, group I) because claims 1-3 are directed to "composition" claims while claim 4 is directed to a "method of use" claim. Should the honorable board not consider the use limitation in the preamble of composition claim 1 to be entitled to patentable weight, Appellants request that the method of use claim (*i.e.*, claim 4) be considered separately as it is well settled that preambles in "methods of use" claims are to be considered part of the claim. (see MPEP §2111.02).

For the above reasons, Appellants respectfully request favorable reconsideration and reversal of the Examiner's rejection of claims 1-4 under 35 U.S.C. §102(b) for anticipation.

Issue 2

The Examiner Has Failed To Establish A Proper 35 USC §103(a) Rejection Over Kakuda '866 in view of Ekanayake '1628

Appellants respectfully request favorable reconsideration and reversal of the Examiner's rejection of claims 5-14 and 16-28 under 35 U.S.C. §103 for obviousness for the following reasons.

Present Invention

The present invention, as recited in claim 5, relates to a method of promoting sleep comprising administering to a patient suffering from a sleep disorder a composition comprising sugar, L-theanine, flavor and tartaric acid (page 1, lines 7-9, page 13, lines 1-7).

Disclosure of Kakuda '866

Kakuda '866 discloses a caffeine stimulation inhibitor that is said to inhibit stimulation by combining the use of theanine extracted from tea leaves and/or a substance having theanine for its major active ingredient which is produced by extracting tea leaves with a solvent such as water, hot water or ethanol, chemical synthesis, microbial fermentation or plant tissue culturing. These active ingredients are said to be able to inhibit the stimulatory action of caffeine without degrading the quality, such as the flavor and aroma, of caffeine-containing beverages and foods, allowing persons hypersensitive to caffeine

to consume caffeine-containing beverages and foods without worry over its effects (see the abstract).

Disclosure of Ekanayake '1628

Ekanayake '1628 discloses a process for the production of tea extracts comprising the steps of (a) extracting tea materials with water, (b) mixing the extract containing solution with protein, (c) acidifying the protein containing extract, and (d) separating the precipitates formed. The resultant tea extracts is said to have reduced bitter and astringent flavors and low levels of polymerized or oxidized flavanols. The extracts are said to be suitable for use as beverages or can be blended with fruit flavors, fruit juices and other flavors (see the abstract).

Ekanayake '1628 further discloses that one of the objects is to provide a beverage which contains caffeine and which provides the alertness benefit of caffeine along with the beneficial effects of the flavanols and other green tea solids (see column 2, lines 6-10).

Reasons to Reverse the Rejection over Kakuda '866 in view of Ekanayake '1628

In this section of the brief, the arguments are arranged so that if an argument makes no mention of a particular group, it applies to all of the rejected claims (and thus, all of the

groups). When specific groups are stated, the arguments in those sections refer to those specific groups. Moreover, if it is stated that the arguments of a first group apply to a second group, any third or subsequent group that states that the arguments of the second group apply, also has the arguments of the first group apply, where applicable.

Failure of the Examiner to make a *Prima Facie* case

Appellants assert that the Examiner has failed to make out a *prima facie* case of obviousness with regard to the 35 USC §103(a) rejection over Kakuda '866 in view of Ekanayake '1628. Three criteria must be met to make out a *prima facie* case of obviousness.

- 1) There must be some suggestion or motivation, either in the references themselves or in the knowledge generally available to one of ordinary skill in the art, to modify the reference or to combine reference teachings.
- 2) There must be a reasonable expectation of success.
- 3) The prior art reference (or references when combined) must teach or suggest all the claim limitations.

See MPEP §2142 and *In re Vaeck*, 20 USPQ2d 1438 (Fed. Cir. 1991).

Appellants respectfully submit that the Examiner has failed to meet any of the above-described elements to make a proper *prima facie* case.

First, there is no suggestion or motivation, either in the references themselves or in the knowledge generally available to one of ordinary skill in the art, to modify the reference or to combine reference teachings. Although theanine is mentioned in both Kakuda '866 and Ekanayake '1628 (see, for example, the abstract in Kakuda '866 and column 1, lines 51-55 in Ekanayake '1628), the purpose of ingesting theanine enumerated in Kakuda '866 would preclude joining theanine with the composition disclosed in the Ekanayake '1628 reference. The Examiner, in this regard, uses Kakuda '866 for the teaching of sleep promotion and Ekanayake '1628 for the teaching of other ingredients in the composition. Please see page 4, line 14 to page 5, line 19 in the Office Action of June 25, 2003.

Applicants submit the purpose of theanine disclosed in Kakuda '866 is to suppress the effects of caffeine (please see column 2, lines 56-60 in Kakuda '866) whereas the purpose of the composition in Ekanayake '1628 is to provide a beverage which contains the alertness benefit of caffeine along with the beneficial effects of the flavanols and other green tea solids (please see column 2, lines 6-9 in Ekanayake '1628). Thus, Kakuda '866 has as an object the suppression of the effects of caffeine whereas Ekanayake '1628 has as an object no suppression of the effects of caffeine. Accordingly, in reading these passages, one of ordinary skill in the art would not combine the teachings of these references. In other words, one would not

use the theanine as taught by Kakuda '866 with the combination of elements that the Examiner asserts is taught by Ekanayake '1628.

Group III - claims 5-7, 11, and 16-18

Thus, claim 5, which is placed in group III cannot be rendered obvious because Kakuda '866 cannot be properly combined with Ekanayake '1628. In addition to the immediately above arguments, Appellants respectfully request that the arguments made in group II also apply here. Claim 5 recites:

5. *A method of promoting sleep comprising administering to a patient suffering from a sleep disorder a composition comprising sugar, L-theanine, flavor and tartaric acid.*

Kakuda '866 fails to disclose or remotely suggest sugars, flavoring, or tartaric acid. Ekanayake '1628 fails to disclose or suggest a method of promoting sleep. Accordingly, because both Kakuda '866 and Ekanayake '1628 lack elements of claim 5 and they cannot be properly combined, Kakuda '866 and Ekanayake '1628 cannot render *prima facie* obvious the claims of group III.

Moreover, Appellants submit that the Examiner's motivation for combining the references is inapposite. Regarding the motivation for combining the references the Examiner states:

Therefore, it would have been obvious for one of ordinary skill in the art at the time the invention was made to combine the teachings of Kakuda with Ekanayake since Ekanayake teaches a theanine containing composition comprising various sugars, minerals, acids and flavorings because they could aid in obtaining a product that is less astringent and less harsh in tastes [SIC, taste] and

provides all of the benefits of green tea solid mixtures and similarly, Kakuda teaches a composition comprising theanine extracted from tea leaves and/or a substance having theanine as its main active ingredient, wherein the caffeine stimulation inhibitor is added to various beverages and foods. (emphasis added, see the Office Action of June 25, 2003 at page 5, line 20 to page 6, line 6)

In particular, Appellants draw attention to the Examiner's motivation wherein the Examiner says the motivation of adding the ingredients taught in Ekanayake '1628 is "because they could aid in obtaining a product that is less astringent and less harsh in tastes". Appellants respectfully point out the following passage from Kakuda '866:

The caffeine stimulation inhibitor that inhibits stimulation by combining the use of theanine extracted from tea leaves and/or a substance having theanine for its major active ingredient which is produced by extracting tea leaves with a solvent such as water, hot water or ethanol, chemical synthesis, microbial fermentation or plant tissue culturing. These active ingredients are able to inhibit the stimulatory action of caffeine without degrading the quality, such as the flavor and aroma, of caffeine-containing beverages and foods, allowing persons hypersensitive to caffeine to consume caffeine-containing beverages and foods without worry over its effects. (emphasis added, see the abstract in Kakuda '866)

Appellants point out that Kakuda '866 specifically points out that theanine can be added to beverages and food **without degrading the quality, such as the flavor and aroma.** Thus, Appellants believe that the Examiner's motivation for adding the sugars, flavorants, and other natural products as disclosed in Ekanayake '1628 is erroneous. If the foods and beverages as disclosed in Kakuda '866 are not astringent when one adds

theanine to them, that is, they do not have a degraded flavor and aroma when theanine is added to them, one would have no motivation to add the sugars, flavorants, and other natural products as disclosed in Ekanayake '1628 to make them less astringent. Accordingly, the Examiner's motivation is inapt. Thus, one of ordinary skill in the art would never combine the teachings of Kakuda '866 and Ekanayake '1628.

Second, there can be no reasonable expectation of success if one cannot properly combine the references. This is because if one cannot properly combine Kakuda '866 and Ekanayake '1628, one simply does not even disclose or suggest all of the elements of the claims. Therefore, success cannot be expected.

Third, even if the references are combined, the references fail to disclose or suggest all of the limitations of the instant claims. Neither Kakuda '866 nor Ekanayake '1628 disclose or suggest sleep promotion. In this regard, the Examiner asserts that "Kakuda disclose a composition that is generic to the issue of sleep-promotion." (see page 6 of the Office Action of June 25, 2003). Appellants strongly disagree. Kakuda '866 simply discloses a caffeine stimulation inhibitor containing theanine. In particular, Kakuda '866 discloses:

By refining theanine, frequently contained in caffeine-containing beverages and foods such as tea and coffee, and using it as an active ingredient, in addition to it being able to be used as a harmless additive, by using theanine and/or compositions having theanine as their active ingredient in caffeine-containing beverages and foods, a caffeine stimulation inhibitor can be provided that allows

those people who are hypersensitive to caffeine or those people who desire to suppress the action of caffeine (including, but not limited to, those people who desire to drink tea and coffee without impairing sleep) without worry over its effects.

Although the caffeine stimulation inhibitor of the present invention is preferably used as an additive of beverages and foods after processing into liquid, granule or powder form, it may also be individually absorbed in the form of tablets, capsules, granules or syrup. (see column 2, lines 57-63 in Kakuda '866).

From this passage, it should be apparent that Kakuda '866 says nothing of "sleep promotion" (or any variant thereof), which appears in independent claims 1, 4, 5, and 21. Because all of the other claims are dependent from these claims, they also contain this element.

Appellants respectfully point out that there are other elements which are not disclosed by the combination of the references. Again, claim 5 recites:

5. A method of promoting sleep comprising administering to a patient suffering from a sleep disorder a composition comprising sugar, L-theanine, flavor and tartaric acid.

Neither of Kakuda '866 or Ekanayake '1628 disclose or remotely suggest "a sleep disorder". In particular, neither Kakuda '866 nor Ekanayake '1628 mention the words "disorder", "disease", or any other related words.

Appellants submit that there are many causes of sleep disorders. Ingesting caffeine is not one of them. Kakuda '866 says nothing of sleep disorders and says nothing about promoting sleep. Thus, Kakuda '866 cannot be deemed to be generic for

sleep-promotion as asserted by the Examiner. Ekanayake '1628 does not even mention the word "sleep". Thus, the combination of Kakuda '866 and Ekanayake '1628 cannot render obvious the instant invention because Kakuda '866 and Ekanayake '1628 fail to disclose the elements of the instant invention. The Examiner has failed to make a proper *prima facie* case of obviousness. For this reason alone, reversal of the Examiner is warranted and respectfully requested.

Moreover, regarding disorders, on page 6 of the Office Action of June 25, 2003 the Examiner asserts:

Furthermore, the particular sleep disorder does not impart patentability since the affect desired by the applicant has been shown to be obtained by the prior art.

Nowhere does Kakuda '866 disclose or suggest any sleeplessness problems that are not caused by caffeine. Appellants fail to see where any generic or specific disclosure of promoting sleep due to sleep disorders appears in Kakuda '866. Moreover, Kakuda '866 fails to disclose or suggest any patients that have a sleep disorder. Accordingly, Appellants submit that the effects of the present invention are neither disclosed nor suggested by Kakuda '866. For the above reasons, Appellants submit that reversal of the rejection is warranted and respectfully requested.

Even if the Examiner had made a proper *prima facie* rejection over the combination of Kakuda '866 and Ekanayake '1628 (which Appellants do not concede), the following arguments

are provided showing why the combination of Kakuda '866 and Ekanayake '1628 cannot render obvious the instant invention.

Group IV - claims 8 and 9

Regarding group IV, Appellants note that claim 8 is dependent from claim 4. Claims 4 and 8, respectively, recite:

4. *A method for promoting sleep in an individual having sleep disorders, comprising administering an effective sleep promoting amount of theanine to the individual having sleep disorders.*

8. *The method according to claim 4, wherein said sleep disorders are those caused by changes in a body rhythm.*

Claim 4 has been rejected under 35 USC §102(b) as being anticipated by Kakuda '866 whereas claim 8 has been rejected under 35 USC §103(a) as being rejected by Kakuda '866 in view of Ekanayake '1628. Thus, the arguments as made in group II apply here.

As disclosed above, one of the requirements to make a *prima facie* case of obviousness is that the prior art reference (or references when combined) must teach or suggest all the claim limitations. To make a proper anticipation rejection all of the elements in the claim must be present in the cited art. Because claim 8 was not rejected under 35 USC §102(b) as being anticipated by Kakuda '866, Appellants submit that the Examiner has implicitly acknowledged that Kakuda '866 does not disclose sleep disorders caused by changes in body rhythm as appears in

claim 8. Because this is the only additional element in claim 8 that does not appear in claim 4, the Examiner has acknowledged that a body rhythm disorder does not occur in Kakuda '866. Otherwise, the Examiner would have rejected claim 8 under 35 USC §102(b) as being anticipated by Kakuda '866 (or at least rendered obvious solely by Kakuda '866).

Appellants assert that Ekanayake '1628 fails to make up this deficiency (i.e., Ekanayake '1628 fails to disclose body rhythm sleep disorders). In particular, nowhere in Ekanayake '1628 is the word "sleep" mentioned. Moreover, nowhere in Ekanayake '1628 do the words "disease", "disorder", or "body rhythm" appear.² Accordingly, the combination of Kakuda '866 and Ekanayake '1628 cannot render obvious claim 8. Claim 9, which is dependent from claim 5, also claims a sleep disorder that is caused by changes in body rhythm. Accordingly, claim 9 also cannot be rendered obvious by the combination of Kakuda '866 and Ekanayake '1628.

Moreover, regarding group IV, Appellants also respectfully submit that neither of claims 8-9 can be rendered obvious by the combination of Kakuda '866 and Ekanayake '1628 because neither of these references remotely mention changes in body rhythm, insomnia, vigilance in middle of sleep, or vigilance in early morning as appears in these claims. Thus, for this reason also,

the rejection over the claims in group IV should also be reversed.

Group V - claim 10

Similar to the above argument regarding group IV, group V is also improperly rejected. Regarding group V (*i.e.*, claim 10, which is dependent from claim 1), the Examiner has rejected claim 1 under 35 USC §102(b) as being anticipated by Kakuda '866 and claim 10 under 35 USC §103(a) as being unpatentable over Kakuda '866 in view of Ekanayake '1628. Claim 10 recites:

10. The composition of claim 1, wherein the theanine is administered in an amount of from 50 to 100% by weight.

Thus, the Examiner has implicitly acknowledged that theanine administered in an amount that is from 50 to 100% by weight as claimed in claim 10 is not disclosed by Kakuda '866. This is the only additional element present in claim 10 that is not present in claim 1 (accordingly, the arguments of group I apply). Appellants submit that the Examiner would have rejected claim 10 as being anticipated or rendered obvious by Kakuda '866 alone if Kakuda '866 had taught this element (*i.e.*, theanine administered in an amount of from 50 to 100% by weight). The Examiner did not.

² Appellants acknowledge that the word "body" does appear in Ekanayake '1628 but the reference to "body" only refers to sugars providing "body" to a beverage. Please see column 7, lines 22-23 in Ekanayake '1628.

Ekanayake '1628 does not make up the deficiency present in Kakuda '866. In particular, Ekanayake '1628 does not disclose any weight percent of theanine relative to the entire composition that is remotely close to that claimed in claim 10 (i.e., 50 to 100 % by weight). This is evident when one looks at Example III in Ekanayake '1628 (see column 11, lines 1-20) where the % by weight of the various ingredients is disclosed. The composition has 75.68 % by weight water, which means at most 24.32 % by weight can be solid, with most of this solid being sugars or acid. (Please note that theanine is a solid at atmospheric pressure and room temperature). Thus, there is no disclosure of theanine in an amount that is close to 50 % to 100 % by weight. Moreover, at column 6, lines 2-5, Ekanayake '1628 states:

The extract may be concentrated to a concentration of tea solids of from about 2% to about 65%, preferably from about 3% to about 55%, more preferably from about 35% to about 50%.

From this passage, it should be evident that with a most preferred amount of tea solid extract that is from about 35% to about 50%, Ekanayake '1628 appears to teach away from administering theanine in an amount that is from 50 to 100 % by weight. This is particularly true when one considers all of the extracts that Ekanayake '1628 mentions are present in, for example, Example IV (in Ekanayake '1628, see column 11, lines 1-20). Accordingly, the rejection is inapposite. Reversal of

Examiner with respect to group V is warranted and respectfully requested.

Group VI - claims 12-14 and 19

Group VI is directed to composition claims that are directly dependent or indirectly dependent from claim 1. Thus, the arguments present in group I apply. Claim 12, a member of group VI, recites:

12. The composition of claim 1, wherein the composition further comprises a mineral.

Appellants have placed these claims into their own group because they are composition claims. Should the preamble of claim 1 not be read into claim 1 (i.e., a sleep promoting composition), Appellants request that these claims be considered separately so as to not affect the patentability of the method claims, wherein it is well settled that the preamble is part of the claim. However, should the honorable Board read the preamble into claim 1, Appellants submit that because there is no motivation to combine Kakuda '866 and Ekanayake '1628, as was explained above, a *prima facie* case of obviousness has not been made with respect to the claims in this group. Kakuda '866 fails to disclose a mineral and Ekanayake '1628 fails to disclose sleep promotion. Thus, reversal of the Examiner's rejection with respect to group VI is warranted and respectfully requested.

Group VII - claims 20 and 28

Claim 20, a member of group VII recites:

20. *The method of claim 5, wherein the composition is administered at a dose of 0.2 to 200 mg/kg weight.*

Thus, in addition to the arguments that apply to group III (of which claim 5 is a member), the following arguments apply.

Regarding group VII (*i.e.*, claims 20 and 28), Appellants respectfully point the honorable board to column 3, lines 20-46 in Kakuda '866 wherein mice were given theanine in amounts of either 174 mg/kg (group C) or 1740 mg/kg (group D). The group C mice appeared to demonstrate the exact same effects as the mice that were given no theanine but given caffeine (group B). The group C mice showed higher spontaneous movement than the control mice (group A - *i.e.*, those mice that were given neither caffeine nor theanine). Please see lines 25-29 in column 3. This demonstrates that theanine in a concentration of 174 mg/kg is not effective in inhibiting the effect of caffeine. The mice that were given 1740 mg/kg (group D) appear to exhibit the same effects as the control mice (group A - those that were given neither caffeine nor theanine) but considerably less than the mice that were given either caffeine alone (group B) or the mice that were given caffeine and theanine at 174 mg/kg (group C). The conclusion one could draw is that theanine is effective if the dosage is increased 10 fold to 1740 mg/kg but is ineffective at a dose of 174 mg/kg.

Appellants respectfully point out that claim 28 claims a dosage of 0.2 to 200 mg/kg. The dosage of theanine that is ineffective in Kakuda '866 (174 mg/kg) falls within this range. The dosage of theanine that is effective (1740 mg/kg) falls way outside of this range. Thus, it appears that Kakuda '866 appears to teach away from using theanine at a concentration that is claimed in claim 28. For this reason, Appellants request reconsideration and reversal of the Examiner with respect to group VII.

Group VIII - claims 21 and 25-27

Similar to group V (of which the arguments in group V apply), group VIII also contains disorders (i.e., changes in body rhythm, insomnia, vigilance in middle of sleep, and vigilance in early morning) in addition to disturbance of restful sleep. Claim 21, a claim in group VIII, recites:

21. *A method for promoting sleep in a human having a sleep disorder, comprising: administering to a human an effective amount of theanine to moderate or ameliorate a sleep disorder selected from the group consisting of insomnia, vigilance in middle of sleep, vigilance in early morning and disturbance of restful sleep.*

Appellants respectfully request that the claims in this group be considered separately from the claims in groups IV and IX in case the honorable board should consider "disturbance of restful sleep" to be an effect of caffeine. The element "disturbance of

"restful sleep" occurs in group VIII, but does not occur in the claims of group IV or IX.

Moreover, regarding group VIII, Appellants submit that the combination of Kakuda '866 and Ekanayake '1628 fail to render obvious the instant invention because Kakuda '866 and Ekanayake '1628 cannot be properly combined as argued above. Moreover, neither Kakuda '866 nor Ekanayake '1628 disclose or suggest moderating or ameliorating sleep disorders. Neither of Kakuda '866 nor Ekanayake '1628 disclose or remotely suggest any sleep disorders. Further, neither of Kakuda '866 nor Ekanayake '1628 disclose or suggest sleep promotion as discussed above. For these reasons, Appellants submit that reversal of the Examiner with respect to the claims in group VIII is warranted and respectfully requested.

Group IX - claims 22-24

The arguments that have been presented in group VIII (as do the arguments presented in group V) apply to group IX. Claim 22, which is a member of group IX, recites:

22. *The method of claim 21, wherein said human suffers from insomnia.*

Appellants respectfully submit that none of claims 22-24 can be rendered obvious by the combination of Kakuda '866 and Ekanayake '1628 because neither of these references remotely mention changes in body rhythm, insomnia, vigilance in middle of sleep,

or vigilance in early morning as appears in these claims. Thus, the rejection over the claims in group IX should be reversed. As was pointed out above in the arguments regarding group VIII, Appellants respectfully request that the claims in this group be considered separately from the claims in groups IV and VIII in case the honorable board should consider "disturbance of restful sleep" to be an effect of caffeine (as appears in group VIII). This element is not present in the claims of group IX. Accordingly, reversal of the Examiner with respect to group IX is warranted and respectfully requested.

Therefore, in light of the above remarks, Appellants believe that proper case of obviousness has not been made for any of claims 5-14 and 16-28. Reversal of the Examiner regarding all the rejections is warranted and respectfully requested.

IX. Conclusion

For the reasons advanced above, it is respectfully submitted that all claims in this application are allowable. Thus, favorable reconsideration and reversal of the Examiner's rejection of claims 1-4 under 35 U.S.C. §102(b) for anticipation and claims 5-14 and 16-28 under 35 U.S.C. §103, for obviousness, by the Honorable Board of Patent Appeals and Interferences, is respectfully solicited.

The required Appeal Brief fee in the amount of \$330.00 is attached hereto.

If necessary, the Commissioner is hereby authorized in this, concurrent, and future replies, to charge payment or credit any overpayment to Deposit Account No. 02-2448 for any additional fees required under 37 C.F.R. §1.16 or under 37 C.F.R. § 1.17; particularly, extension of time fees.

Respectfully submitted,

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Attachment: APPENDIX

X. Appendix (Appealed claims)

1. A sleep-promoting composition comprising theanine.
2. Food comprising the composition of claim 1.
3. A medicament comprising the composition of claim 1.
4. A method for promoting sleep in an individual having sleep disorders, comprising administering an effective sleep promoting amount of theanine to the individual having sleep disorders.
5. A method of promoting sleep comprising administering to a patient suffering from a sleep disorder a composition comprising sugar, L-theanine, flavor and tartaric acid.
6. The method of claim 5, wherein the sugar is granulated sugar.
7. The method of claim 5, wherein the composition further comprises malt syrup.
8. The method according to claim 4, wherein said sleep disorders are those caused by changes in a body rhythm.

9. The method of claim 5, wherein said disorder is that caused by changes in a body rhythm.

10. The composition of claim 1, wherein the theanine is administered in an amount of from 50 to 100% by weight.

11. The method of claim 5, wherein the theanine is administered in an amount of from 50 to 100% by weight.

12. The composition of claim 1, wherein the composition further comprises a mineral.

13. The composition of claim 12, wherein the mineral is a metal salt.

14. The composition of claim 13, wherein the metal salt contains an element selected from the group consisting of iron, magnesium, copper, zinc, selenium, calcium, potassium, manganese, chromium, iodine, molybdenum, nickel, and vanadium.

15. (Canceled).

16. The method of claim 5, wherein the composition further comprises a mineral.

17. The method of claim 16, wherein the mineral is a metal salt.

18. The method of claim 17, wherein the metal salt contains an element selected from the group consisting of iron, magnesium, copper, zinc, selenium, calcium, potassium, manganese, chromium, iodine, molybdenum, nickel, and vanadium.

19. The composition of claim 1, wherein the composition is in the form of a solution or suspension.

20. The method of claim 5, wherein the composition is administered at a dose of 0.2 to 200 mg/kg weight.

21. A method for promoting sleep in a human having a sleep disorder, comprising:

administering to a human an effective amount of theanine to moderate or ameliorate a sleep disorder selected from the group consisting of insomnia, vigilance in middle of sleep, vigilance in early morning and disturbance of restful sleep.

22. The method of claim 21, wherein said human suffers from insomnia.

23. The method of claim 21, wherein said human suffers from vigilance in middle of sleep.

24. The method of claim 21, wherein said human suffers from vigilance in early morning.

25. The method of claim 21, wherein said human suffers from disturbance of restful sleep.

26. The method of claim 21, wherein said effective amount of theanine is administered to said human on a daily basis.

27. The method of claim 21, wherein said theanine is administered in the form of a composition comprising sugar, L-theanine, flavor and tartaric acid.

28. The method of claim 21, wherein the theanine is administered at a dose of 0.2 to 200 mg/kg weight.